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5 **510(k) SUMMARY**

APR 23 2009

(as required by section 807.92(c)

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: (612) 287-4174 Mobile: (612) 226-3040 Fax: (612) 287-4138 Email: usskg@coloplast.com
Name of Contact Person:	Suresh Ghai Regulatory Affairs Manager
Date Prepared:	January 29th, 2009
Trade Or Proprietary Name:	Bonee Needle for Bladder Injections
Common Or Usual Name:	Endoscopic Injection Needle
Classification Name:	Endoscope and accessories (21CFR section 876.1500) (Product Code: FBK) Device Class: 2

Legally Marketed Device To Which Your Firm Is Claiming Equivalence:

The Bonee Needle for Bladder Injections is substantially equivalent in performance, indication, design and materials to Cook Injection Needles from Cook Urological, Inc., cleared under Premarket notification # K022484.

Device Description:

The needle for bladder injections is designed for a working endoscope channel inner diameter of 5 French or larger.
This product is 35 cm (ref: NBI035) or 70 cm (ref: NBI070) length and is made of thermoplastic tubing polyamide (PA) marked by ink, a stainless steel cystoscopic needle, a polyamide Luer Lock connector and a Tuohy Borst adapter to allow connection with the cystoscope.

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The assembly of the different components is being insured by gluing (UV process).

A blue protective cap in Neoplex® is also supplied to prevent cystoscope channel degradation during needle insertion.

Shelf life of the full range of the needle for bladder injections is 2 years.
The needle for bladder injections is provided sterile and is intended for single use.

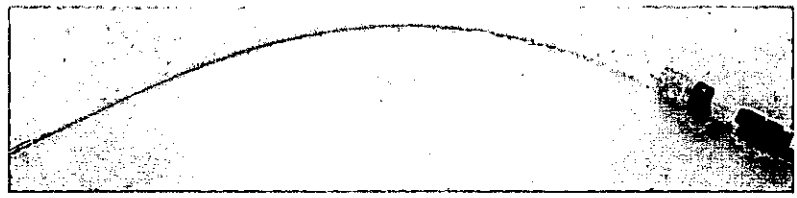


Figure 1: Bonee Needle for Bladder Injections

Product variants available:

Reference	Length (cm)	Use	Body diameter (mm)	Needle tip
NBI035	35	With rigid cystoscope	1.7 mm (= 5 CH/FR)	Chiba tip (22G) 4 mm in length
NBI070	70	With flexible cystoscope		

Table 2: Sizes and codes of the needle for bladder injections

Intended Use Of The Device:

The Bonee Needle for Bladder Injections is used to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.

Technological Characteristics Compared To Predicate Device:

The Bonee Needle for Bladder Injections is substantially equivalent in performance, indication, design and materials to Cook Injection Needles from Cook Urological, Inc., cleared under Premarket notification # K022484.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence is supported by bench testing comparing Bonee Injection needle to the predicate devices and biocompatibility testing performed on the Bonne Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Mr. Suresh Ghai
Regulatory Affairs Manager
Coloplast A/S
1601 West River Road N
MINNEAPOLIS MN 55411

Re: K090217
Trade/Device Name: Bonee Needle for Bladder Injections
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: April 2, 2009
Received: April 3, 2009

Dear Mr. Ghai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

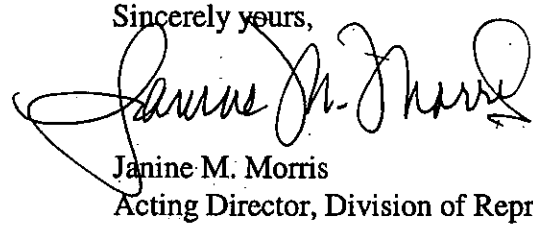
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K090217

Device Name: Bonee Needle for Bladder Injections

Indications for Use:

The Bonee Needle for Bladder Injections is used to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090217